

REMARKS

The present application is a continuation-in-part of International Patent Application No. PCT/US00/14840 filed 26 May 2000, and claims the benefit of U.S. Provisional Patent Application No. 60/252,536 filed 22 November 2000. Claims 1-20 stand rejected. Claims 18-20 have been cancelled without prejudice to consideration in a continuing application. Claims 21-30 have been added to define further inventive aspects of the present application. A check is enclosed in the amount of claim fees for seven additional claims with one being of independent form. Reconsideration of the present application as amended is respectfully requested.

Claims 1-8, 10-15, and 18-20 were rejected under 35 USC § 102(b) as being anticipated by U.S. Patent Number 5,034,013 to Kyle et al. (the "Kyle reference"). The applicant traverses. In order to establish anticipation, each and every element and limitation of the subject claim must be disclosed in a single reference. The Kyle reference is directed to "a tubular intramedullary nail having an elongated body with a proximal head portion, an intermediate portion and a distal end portion. The nail is formed of a rod material with a centrally located longitudinal bore extending therethrough." (Kyle reference, column 2, lines 4-8). This bore results in "a hollow elongated body" of the nail (Kyle reference, column 3, lines 32-33) (emphasis added), that "extends throughout the length of the nail ... [and]... "not only provides added flexibility to the nail but also provides for the reception of a guide wire which aids in the insertion of the nail into the bone canal." (Kyle reference, column 3, lines 42-46). This hollow nail configuration is disclosed in both of Kyle's embodiments for femoral (Figs. 1-8) and tibial (Figs. 9-12) intramedullary applications, respectively. (See Kyle reference, column 4, lines 33-54).

In contrast, features of independent claim 1 that the Kyle reference fails to disclose include a solid central section that is not hollow.

With regard to the inherency rejection of claims 10-15, an inherent claim element must "necessarily be present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." In re Robertson, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citing Continental Can Co. v. Monsanto Co., 948 F2d 1264, 1268 (Fed. Cir. 1991)). Indeed, inherency "may not be established by probabilities or possibilities . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient." 49 USPQ2d at 1951. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 464 (USPTO Bd. of Pat. App. and Interferences 1990) (emphasis in the original). For independent claim 10, "providing an elongate member having a solid central section having a cross sectional dimension and having proximal and distal fastener receiving areas of increased cross sectional dimension relative to the cross sectional dimension of the central section" are among its features that are not disclosed by the Kyle reference, and not inherent to it. The dependent claims rejected as being anticipated are patentable for at least the same reasons as the corresponding base claims.

Indeed, there are several further reasons supporting patentability of dependent claims. For example, dependent claim 5 recites proximal and distal bends at acute angles on the same side of the sagital plane as shown in the nonlimiting example of Fig. 3 of the present application. This "same side" bend configuration is not disclosed in connection with the femoral nail embodiment of Figs. 1-8 nor the tibial nail embodiment of Figs. 9-12 of the Kyle reference.

In another example, nowhere in the Kyle reference is the ratio of claim 6 disclosed. It is well-settled that the Patent Office should not rely on dimensionally scaling a patent drawing figure where such drawing figure is not otherwise stated as being drawn to scale nor dimensionally accurate. The Court of Appeals for the Federal Circuit has recently reaffirmed this position stating “[u]nder our precedent, however, it is well established that patent drawings do not define the precise proportions of the elements and may not be relied upon to show particular sizes if the specification is completely silent on the issue.” Hockerson-Halberstadt, Inc. v. Avia Group International, Inc., 55 USPQ2d 1487, 1491 (Fed. Cir. 2000) (*citing In re Wright*, 193 USPQ 332, 335 (CCPA 1977)).

In still other examples, the bending features of claims 13 and 14 for distal and proximal receiving areas to conform to right and left femurs is not inherent in the Kyle reference. In fact, the only proximal angling taught by Kyle appears to be in connection with the embodiment directed to the tibia of Figs. 9-12. Such features are not "necessarily present" as required for inherency, because Kyle's nails 10 or 100 can be used in alternate ways. For instance, these devices can be used without bends in both the proximal and distal end regions.

In a further example, claim 15 includes an "insertion point on the greater trochanter lateral of the piriformis fossa." As explained, for example, on page 6, lines 4-17 of the present application -- this insertion point is not the one commonly used for femoral intramedullary nails. In contrast, the Kyle reference appears silent as to the identity of any insertion point. Consequently, the features of claim 15 cannot be an implicit necessity of the Kyle reference disclosure; and are therefore not inherent therein.

Dependent claim 9 was rejected under 35 USC § 103(a) as being unpatentable over the Kyle reference in view of U.S. Patent Number 5,019,079 to Ross (the "Ross reference"). "To establish a

prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." Manual of Patent Examining Procedure (MPEP) §2142 (*citing In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Moreover, the suggestion/motivation to combine or modify under §103 needs to be specific. Where a "statement is of a type that gives only general guidance and is not specific as to the particular form of the claimed invention and how to achieve it ... [s]uch a suggestion may make an approach 'obvious to try' but it does not make the invention obvious." *Ex parte Obukowicz*, 27 USPQ2d 1063, 1065 (U.S. Pat. and Trademark Off. Bd. of Pat. App. & Interferences 1993) (*citations omitted*).

The anchoring function goal for the Kyle device may not always be well-served by a compression screw of the type disclosed in the Ross reference. To the contrary, it would typically be preferred to laterally anchor a intramedullary nail through an integral bone site, rather than to pull together fragments to serve as a nail anchor. Thus, it is respectfully submitted that the requisite motivation to combine the references in the manner asserted is absent.

Claims 16-17 were rejected under 35 USC § 103(a) as being unpatentable over the Kyle reference in view of U.S. Patent Number 4,862,883 to Freeland. The features of independent claim 16 include a solid central section which is not disclosed by the Kyle reference as previously explained in connection with claim 1. Claim 17 is patentable for at least the same reasons. Accordingly, it is respectfully submitted that claims 1-17 should be allowed.

Claims 21-30 have been added further defining inventive aspects of the present application. Claims 21-23 depend from independent claim 1. Dependent claim 21 is directed to an alternative embodiment in which at least two fastener holes are normal to one another and the longitudinal axis--as described, for example, in connection with Fig. 12 of the present application. Dependent claim 22 is directed to features discovered to at least sometimes be desired for application of the invention to children as explained on page 9, lines 4-14 of the present application. Dependent claim 23 is directed to certain optional geometric features of the present invention that are inapposite to the longitudinal grooves (fluting) found in nails 10 and 100 of the Kyle reference. These features are supported on page 11, lines 11-14 of the present application.

Dependent claims 24 and 25 further define inventive aspects of independent claim 10 with unique features corresponding to those explained in connection with claims 21 and 23, respectively.

Independent claim 26 includes further inventive features such as solid material spanning across a central region of the cross section for the central section, among others. Claims 27-30 depend from claim 26 defining further inventive aspects, as well. The inventions of claims 21-30 are not taught, suggested, or disclosed by the art of record.

In view of the foregoing, it is believed that claims 1-17 and 21-30 are in condition for allowance. Reconsideration of the present application as amended is respectfully requested. The Examiner is encouraged to contact the undersigned to resolve any outstanding matters concerning the present application.

Respectfully submitted:



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